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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,536	06/29/2000	Earl A. Hubbell	AFFYP007X1C1	1335
26541	7590	05/10/2004	EXAMINER	
RITTER, LANG & KAPLAN 12930 SARATOGA AE. SUITE D1 SARATOGA, CA 95070			FREDMAN, JEFFREY NORMAN	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/607,536	<b>Applicant(s)</b> HUBBELL ET AL.	
	<b>Examiner</b> Jeffrey Fredman	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-10 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-10 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The rejection of claims 8-10 and 24-26 under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendment.

### ***Claim Interpretation***

2. The central question posed by the amendment is what structural difference is imposed upon the substrate. The one clear structural difference is that the claim is not limited to the substrate with linked probes, but the claim now also encompasses labeled probes which are hybridized to the substrate. The other clear structural limitation is that at least one of the polymer probes must have a lower hybridization (intensity?) relative to some other probe. However, as will be noted in the response to arguments, while this amendment does impose some additional structure to the substrate, it does not distinguish from the prior art because the claim limitation regarding the term "control" targets is not given patentable weight. That is, the term "control" does not structurally distinguish one probe from another, so any probe which is linked to the substrate may be termed a "control". Further, the newest limitation which requires at least two different sequences is also met by the prior art.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 8-10 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Chee et al (U.S. Patent 5,837,832).

Chee teaches a substrate (column 6, lines 14-34, with nucleic acid probes coupled onto the membrane (see column 14, lines 14-34 and figure 26, for example) comprising:

a) a plurality of regions on the substrate in which diverse polymer probes are coupled in a checkerboard pattern, such as every overlapping 17 mer probe from exon 5 of the p53 tumor suppressor gene as well as four additional probes with each possible substitution at base 7 were also placed on the array (see figure 26 and column 23, lines 13-28) and,

b) a plurality of regions on the substrate in which the polymer probes having the same sequence are coupled and the array also clearly has many regions in which polymer probes having the same sequence are coupled, but where there are clearly sequences on the array that could bind to the same control monomer sequence but which are different in their actual sequence (see figure 26 and column 23, lines 13-28). For example, as shown in column 26, lines 45-50, when overlapping probes are made, they share all of their sequence but one nucleotide. Thus, the probes of Chee have probes which can bind to the same 16 mer target probe, since they share that entire region, but which differ in actual sequence. Further, as noted in column 23, Chee expressly also places additional probes with each possible substitution. For each probe, one of these four probes will be identical to the wildtype, yielding a situation where two identical probes are paired. Figure 27 makes this perfectly clear. In the first row, where

there is a T at the first position, the WT probe and the bottom probe would be identical, since both would have a T. There would be three different probes, which share 16/17 nucleotides, differing at position 7 with either an A, C, or G instead of a T. These would have been made with different monomer addition cycles and in any case, the products are not different however they are made.

***Response to Arguments***

5. Applicant's arguments filed March 26, 2004 have been fully considered but they are not persuasive.

Applicant argues that Chee does not teach a substrate with the labeled control targets which are hybridized in a way that results in a lower hybridization of one probe relative to other probes. This argument is not persuasive because it gives, as noted in the claim interpretation paragraph, too much weight to the term "control". As noted in the rejection, column 23 of Chee provides an example in which labeled probes (doubly labeled with fluorescein and biotin) were hybridized to the substrate which had four bound polymer probes that were identical except at one position. These labeled probes had a lower hybridization to three of the four bound polymer probes relative to the fourth bound polymer probe. This is exemplified in figures 26 and 27. So the hybridized array of Chee, as taught in Column 23, meets the new claim limitation. Therefore, the prior art rejection is maintained.

The fundamental issue is whether there is any structural difference between the claims and Chee. In fact, there is not. The claims require a structure of probes where some are different and Chee teaches such a structure. The remainder of the claim

represents intended use recitations. As MPEP 2111.02 notes "Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." It is clear that a structural difference must exist between the claimed invention and the prior art to overcome the rejection and not simply a difference in the intended use. As MPEP 2111.02 also notes "a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone."

Here, no such structural difference exists. Therefore, the prior art rejection is maintained.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

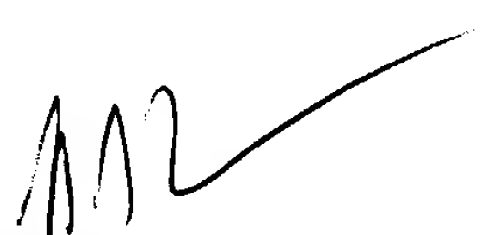
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jeffrey Fredman  
Primary Examiner  
Art Unit 1637  
